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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,809	09/15/2003	Magnus Hook	P07741US01/BAS	7385

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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,809	HOOK ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-8,10-13,27 and 29-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,14,19-26 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group III, claims 9, 14, 19-26 and 28, wherein the antibodies bind to the EF 1093 protein as set forth in SEQ ID NO: 13, in the reply filed on 6/20/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-8, 10-13, 27 and 29-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Objections

2. Claims 9, 14, 19-26 and 28 are objected to because of the following informalities: the claims depend from non-elected claims which have been withdrawn from consideration. The claims must be amended. Appropriate correction is required.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, e.g., page 11 at line 14; page 12, line 7, page 45, page 46, page 61, etc.. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code as well as any other hyperlinks the Examiner may have inadvertently missed. See MPEP § 608.01.

4. The use of the trademark MSCRAMM has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112-2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9, 14, 19-26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is dependent on non-elected claim 6 which recites a protein which is identified by a generic method. The generic method fails to identify the structure of the protein recited in the non-elected claim. Zero identifying characteristics for the protein are provided. Accordingly, the structure of the claimed antibody has not been adequately defined in the instant claim. The claims does not sufficiently satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the amino acid sequence of the protein or molecular weight, which would allow for one to identify the protein without ambiguity. Applicants have elected an antibody which specifically binds to a protein consisting of the amino acid set forth in SEQ ID NO: 13; however, the instant claim does not reflect this.

Claims 9, 14 and 19 are vague and indefinite due to the phrase 'antibody that can bind' because the capability of performing the function is not the same thing as

actually performing the function. A positive recitation of the function is required. Suggested claim language includes "which specifically binds".

Claim 14 is dependent on non-elected claim 12 which recites a protein which is identified by a generic method. The generic method fails to identify the structure of the protein recited in the non-elected claim. Zero identifying characteristics for the protein are provided. Accordingly, the structure of the claimed antibody has not been adequately defined in the instant claim. The claim does not sufficiently satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the amino acid sequence of the protein or molecular weight, which would allow for one to identify the protein without ambiguity. Applicants have elected an antibody which specifically binds to a protein consisting of the amino acid set forth in SEQ ID NO: 13; however, the instant claim does not reflect this.

Claim 19 (and 20-26 and 28 which depend from claim 19) is dependent on non-elected claim 16 which recites a protein which is identified by a generic method. The generic method fails to identify the structure of the protein recited in the non-elected claim. Zero identifying characteristics for the protein are provided. Accordingly, the structure of the claimed antibody has not been adequately defined in the instant claim. The claim does not sufficiently satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the amino acid sequence of the protein or molecular weight, which would allow for one to identify the protein without ambiguity. Applicants

have elected an antibody which specifically binds to a protein consisting of the amino acid set forth in SEQ ID NO: 13; however, the instant claim does not reflect this.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 9, 14, 19-26 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Choi et al (US 6,448,043 B1).

Choi et al teach an isolated protein from *Enterococcus faecalis* (EF040 polypeptide #109) which has an amino acid sequence which is 100% identical to the amino acid sequence set forth in Applicants' SEQ ID NO: 13. See sequence alignment available in public PAIR. Choi teaches polyclonal and monoclonal antibodies which bind this protein and the use of the antibodies as reagents in diagnostic kits and as pharmaceutical compositions for the passive immunization against *E.faecalis*. See the paragraph bridging columns 3-4, column 22; column 23, lines 39-67; column 24line 64-column 25, line 67; kits column 30, lines 19-56; and pharmaceutical compositions/methods of passive immunization column 33 line 10-column 34, line 67. Claims 9, 14 and 19 are dependent from non-elected claims drawn to a protein product-by-process claim. The protein comprises SEQ ID NO: 13. Accordingly, an antibody which specifically binds to a protein comprising SEQ ID NO:13 would be expected to be identical regardless of how the protein was obtained, absent evidence to the contrary. "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

9. Claims 9, 14, 19-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi et al (WO 9850554-A2).

Choi et al teach an isolated protein from *Enterococcus faecalis* (EF040 polypeptide #109) which has an amino acid sequence which is 100% identical to the amino acid sequence set forth in Applicants' SEQ ID NO: 13. See sequence alignment available in public PAIR. Choi teaches polyclonal and monoclonal antibodies which bind this protein and the use of the antibodies as reagents in diagnostic kits and as pharmaceutical compositions for the passive immunization against *E.faecalis.* The disclosure is identical to that contained in US Patent No. 6,448043 above. See the paragraph bridging columns 3-4, column 22; column 23, lines 39-67; column 24 line 64-column 25, line 67; kits column 30, lines 19-56; and pharmaceutical compositions/methods of passive immunization column 33 line 10-column 34, line 67 of that US patent. Claims 9, 14 and 19 are dependent from non-elected claims drawn to a protein product-by-process claim. The protein of the non-elected claims comprises SEQ ID NO: 13. Accordingly, an antibody which specifically binds to a protein comprising SEQ ID NO:13 would be expected to be identical regardless of how the protein was obtained, absent evidence to the contrary. "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or

similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

10. Claims 9, 14, 19-26 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al (US 6,617,156 B1).

Doucette-Stamm et al teach an isolated protein from *Enterococcus faecalis* (SEQ ID NO: 6124) which has an amino acid sequence which is 100% identical to the amino acid sequence set forth in Applicants' SEQ ID NO: 13. See sequence alignment available in public PAIR. Doucette-Stamm et al teach polyclonal and monoclonal antibodies which bind this protein and the use of the antibodies as reagents in diagnostic kits and as pharmaceutical compositions for the passive immunization against *E.faecalis.* See column 9, line 7-bottom of column 10; column 40, line 23—top of column 42. Claims 9, 14 and 19 are dependent from non-elected claims drawn to a protein product-by-process claim. The protein of those non-elected claims comprises SEQ ID NO: 13. Accordingly, an antibody which specifically binds to a protein comprising SEQ ID NO:13 would be expected to be identical regardless of how the protein was obtained, absent evidence to the contrary. "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner

provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "an isolated antibody which specifically binds to a protein consisting of the amino acid sequence set forth in SEQ ID NO:13, wherein said antibody *treats E.faecalis* infection in a human or animal", does not reasonably provide enablement for "any antibody which binds to the generic protein of non-elected claim 16 which treats or ***prevents any*** Gram positive bacterial infection in a human or animal". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Instant claim 22 broadly recites that an antibody which binds to the generic protein of non-elected claim 16 which treats or ***prevents any*** Gram positive bacterial infection in a human or animal. However, the claimed antibodies were generated against an *E.faecalis* polypeptide and it is unpredictable and unlikely that these *E.faecalis*-specific antibodies could treat, much less prevent, any Gram positive

bacterial infection. Further, passive immunization with antibodies is known in the art as often an effective means to treat an on-going bacterial infection. However, passive immunization methods generally do not provide long-term protection or prevention of bacterial infection. Passive artificially acquired immunity refers to the injection of antibody-containing serum, or immune globulin, from another person or animal or the injection of monoclonal antibodies. In passive immunization procedures, antibodies made in another person or animal are administered to a patient for treatment of an on-going infection. The body is not making its own antibodies and memory cells are not produced. Generally, any immunity is short-lived. With active immunity, antigens enter the body and the body responds by making its own antibodies and B-memory cells. In this case, immunity is longer lived although duration depends on the persistence of the antigen and the memory cells in the body. The *prevention* of a bacterial infection is extremely difficult and unpredictable. The instant specification provides no examples that the claimed antibody can provide prevention of any Gram positive bacterial infection, much less *E.faecalis*. There are no challenge experiments. The prior art teaches that *E.faecalis* is part of the normal gastrointestinal and genital tract flora in humans, accounting for 80-90% of clinically isolated species. See US Patent 6,617,156, column 1, lines 30-45. The reference teaches that *E.faecalis* is widely distributed in nature, animals and humans (col. 1, lines 30-33). Accordingly, it would be next to impossible to prevent infection of *E.faecalis*. The claim should be amended to 'treatment' since no challenge experiments are provided in the specification.

13. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile

transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

8/14/06

Jennifer Graser
Primary Examiner
Art Unit 1645